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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/177,427 10/22/98 LUKAS S 4804-4

HM22/0828
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551 FIFTH AVENUE
NEW YORK NY 10176

EXAMINER

BERMAN, A

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

08/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/177,427

Applicant(s)

LUKAS ET AL.

Examiner

Alysia Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-8,11 and 13-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8,11 and 13-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

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DETAILED ACTION

1. Receipt is acknowledged of the request for corrected filing receipt filed 24 January 2000, the request for extension of time and amendment filed 05 June 2000 and the information disclosure statement filed 03 July 2000. Claims 1 and 5 have been amended. Claim 4 has been canceled. Claim 15 has been added. Claims 1-3, 5-9, 11 and 13-15 are pending.

Information Disclosure Statement

2. The information disclosure statement filed on 03 July 2000 does not fully comply with the requirements of 37 CFR 1.98 because: the supplied copy is not legible. Since the submission appears to be *bona fide*, applicant is given **ONE (1) MONTH** from the date of this notice to supply the above mentioned omissions or corrections in the information disclosure statement. **NO EXTENSION OF THIS TIME LIMIT MAY BE GRANTED UNDER EITHER 37 CFR 1.136(a) OR (b).** Failure to timely comply with this notice will result in the above mentioned information disclosure statement being placed in the application file with the noncomplying information **not** being considered. See 37 CFR 1.97(i).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3, 5-8, 11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,767,789 ('789).

This rejection is maintained for reasons of record.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,767,789 ('789) as applied to claims 1-3 and 5-7 above, and further in view of US 5,707,646 ('646).

This rejection is maintained for reasons of record.

7. Claims 2, 3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,767,789 ('789) as applied to claims 1-3 and 5-7 above, and further in view of US 4,808,411 ('411).

This rejection is maintained for reasons of record.

Response to Arguments

8. Applicant's arguments filed 05 June 2000 have been fully considered but they are not persuasive.

9. Applicant argues that “the present invention provides sustained release properties when compared to non-coated products,” then argues that “there is no teaching or suggestion that Blank’s product exhibits sustained release properties. Indeed, Blank’s products are immediate release type products. In contrast, the present invention is in a spray dried product which is both sustained release and taste masking.” This is not convincing because the instant claims do not require that the polymer coating be limited to any particular polymer known in the art for providing enteric or sustained release. Further, as Blank et al. are using the same coating polymer, ethyl cellulose, as applicant claims in the same solvent preferred by applicant and applied by the same method as claimed by applicant, it is unclear why the products of Blank and the instant invention would not have similar properties.

Indeed, Blank and the instant independent claims only differ slightly in the amount of polymer coating applied to the pharmaceutically active compounds. It is unclear why use of a slightly greater amount of the polymer would not also produce a taste masked and sustained release product sought by applicant. It is unclear how applicant achieves a slower release than Blank (as he implies) when he is applying less coating. Further, given the taste masking discussed by Blank, it is unclear if applicant’s coated active compound would be taste-masked. If applicant is getting different coating results than Blank by using essentially the same coating process, it must be due to some limitation not present in the claims.

10. Applicants’ argument that his product is sustained release versus immediate release is not convincing because applicant argues that his invention provides “sustained release properties when compared to non-coated products.” If Blank et al. also compared their coated particles to

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non-coated products, then their less than 10 second dissolution time might also be considered sustained release.

Applicant's arguments are not convincing as they do not clarify why the process and coating of Blank would produce a product differing from that claimed given the similarities of the respective coating methods.

11. Applicant argues that there is no motivation to modify the amount of coating in the product of US '789 to less than 23%. However, it is within the skill in the art to select optimal parameters in order to achieve a beneficial effect. Therefore, absent evidence of unexpected and superior results, no criticality is given to the amount of coating.

12. Applicant argues that it is improper to characterize the use of a two fluid nozzle spray dryer as not critical. Absent evidence of unexpected and superior results, it is considered routine and within the skill in the art to use any suitable spray dryer.

13. Applicant argues that US '646 gives no teaching or suggestion of a continuous coating, sustained release or less than 23% coating. Applicant further argues that US '646 uses the spray drying apparatus for cooling. If one has the same components and uses the same process to produce a product, that product would inherently exhibit the same properties. The terms "sustained" versus "immediate" release are relative and do not provide patentability to a product. Therefore, absent evidence of unexpected and superior results, no patentable weight is given to these limitations in the claim.

14. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching,

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suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both references are teaching spray dried particles containing a pharmaceutically active agent coated with ethylcellulose for the purposes of taste masking. US '646 teaches that clarithromycin is suitable for this type of formulation because of its unpleasant taste. Therefore, the motivation to substitute the clarithromycin of US '646 for the acetaminophen of US '789 is to provide more pleasant tasting medicaments.

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). The idea of combining them flows logically from their having been individually taught in the prior art. *In re Crockett*, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960).

15. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to substitute the small particle sizes taught by US '411 in the formulation of US '789 is based on the need for formulations that are more easily administered, for example in suspensions for children.

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16. Further, instant claims 1-3, 5-9 and 13-15 are directed to a product that requires polymer-coated particles that contain at least one pharmaceutically active compound. The process by which the particles are obtained, i.e. spray drying, does not render the particles patentable over the prior art. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

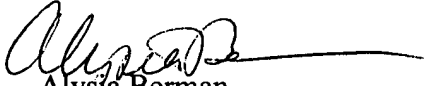
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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703/308-4638. The examiner can normally be reached on Monday through Friday from 8:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703/308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703/305-3704 for regular communications and 703/305-3704 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-1234.


Alysia Berman
Patent Examiner
16 August 2000


DIANA DUDASH
SUPERVISORY PATENT EXAMINER
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